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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,278	07/30/2001	Reginald M. Gorczynski	9579-39	9183

7590 10/27/2004

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,278	GORCZYNSKI ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004 and 01 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 - 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 - 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 06/29/2004 and 09/01/2004 have been entered.

3. It is noted that claim status identifiers are not in compliance with 37 CFR 1.121. The correct identifier for claims 1 – 9 is "cancelled," and for claims 10 – 13 "previously presented." Appropriate correction is required.

4. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Office Action will be in response to applicant's arguments, filed 06/29/2004.

The rejections of record can be found in the previous Office Action, mailed 03/02/2004.

5. Applicant's amendment of claim 14 to correct the dependency of the claims has obviated the rejection of record under 35 USC 112, second paragraph.

6. Claims 10-14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Applicant's arguments, filed 06/29/2004, have been fully considered but have not been found convincing, essentially for reasons of record.

Applicant's arguments and the Examiners rebuttal are essentially the same as of record.. The rejection of record is reiterated below for Applicant's convenience.

As previously noted, the specification provides a working example on pages 83-85 and Figure 24A showing that in mice pre-immunized with a CD86 transfected form of leukemic cells prior to challenge with the wildtype leukemia, administration of an anti-CD200 (anti-OX-2) antibody at the time of wildtype tumor challenge improved survival. However, Figure 24A also shows that the effect was only seen in pre-immunized mice: administration of the antibody in mice without pre-immunization did not improve survival. In addition, the specification notes that no improvement of survival was seen when mice were pre-immunized with CD80 transfected cells, then challenged and given anti-OX-2 antibody.

The specification also provides a working example on pages 91-92 and Figure 30 showing that anti-OX-2 antibody could inhibit the enhancement of lung nodule formation that accompanied the administration of allogeneic leukocytes following I.V. administration of cultured sarcoma cells. However, Figure 30A also shows that administration of anti-OX-2 was not by itself sufficient to reduce the number of lung nodules compared to PBS alone, and Figure 30B shows that the percentage of mice showing no lung nodules after tumor cell administration was actually decreased compared to administration of PBS.

The Examiner previously concluded that although the specification does provide two examples in which tumor growth was inhibited by an antibody to the OX-2 (CD200) molecule, the results appeared to be limited because in neither the pre-immunization model nor the lung nodule formation model did simple administration of the anti-OX-2 antibody appear to have a beneficial effect.

Applicant notes that the differential effects observed depend upon the expression of CD200/OX-2 and that this expression can be determined using the animal immunization model described in the specification or using methods routine in the art. Claim 10 as amended is limited to those cancers that can be treated by reducing, inhibiting or suppressing immune suppression caused by CD200.

However, the specification does not appear to provide sufficient guidance such that the skilled artisan could practice the method without undue experimentation. Although methods exist for determining if a given tumor expresses CD200 or if tumor immunization enhances CD200 expression, the skilled artisan requires sufficient guidance as to which tumor types would be expected to meet these criteria. Post filing date references showing that other cancers besides the working examples described supra express or induce CD200 do not correct for the lack of guidance provided in the specification as filed as to which cancers fall within this genus.

Applicant's comments regarding the therapeutic utility of modulating the CD200 cascade in other systems where immunosuppression is beneficial are acknowledged. However, the instant claims are distinct because they require the enhancement of the immune response (i.e., the immune suppression induced by CD200 is suppressed, providing a new result of enhancement). The rejection of record is with respect to

It is again noted that even when data has been provided suggesting that antibody therapy of a particular tumor type was effective in animal models of particular types of cancers, the state of the art recognized that it was unpredictable if success in

one or a limited number of models could be generalized. Kim et al. (Cancer Res. 2001; 61:2031-2037, of record) and Kjaergaard et al. (Cancer Res. 2000; 60:5514-5521, of record).

Thus in view of the unpredictability associated with the field of monoclonal antibody therapy of cancer and the lack of sufficient guidance as to which cancers involve CD200-mediated suppression, there does not appear to be enabling support for the instant methods.

7. Conclusion: no claim is allowed.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

October 20, 2004

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
10/25/04